

510 (k) Summary Statement**Submitter:**

Kinetic Concepts, Inc.
P.O. Box 659508
San Antonio, TX 78265
Judith A. Harbour
210-255-4468
210-255-4440 FAX

Date of Submittal:

July 1, 1999

Name of Device:

V.A.C. PLUS

Classification Name:

Powered Suction Pump
(per 21 CFR 878.4780)

Substantial Equivalence:

V.A.C. Plus, 510(k) No. 945062

Device Description:

This notification for The V.A.C. Plus device is for **labeling changes** only, as have evolved over time. There have been no significant modifications or design changes to the presently cleared and marketed V.A.C. Plus device, 510(k) No. K945062.

The labeling changes have not been fully itemized, but include changes in the listing of specific wound types addressed.

Indications for Use:

The V.A.C. Plus is "a powered suction pump that is intended for use on patients who would benefit from a suction device, particularly as the device may promote wound healing, including patients who would benefit from vacuum assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or alternating (also referred to as intermittent) suction pressures."

Within this broad application of the therapy to all wound types, acute, chronic, traumatic, subacute and dehiscent wounds and ulcers are but only a few types of wounds that fall within the cleared intended use of the V.A.C. Plus.

Clinical Studies to Support Labeling Claims:

A wound is defined as "(1) trauma to any of the tissues of the body, especially that caused by physical means and with interruption of continuity and (2) a surgical incision." See *Stedman's Medical Dictionary* (26th ed.). The adjectives used to describe wounds, such as "acute" (a brief health effect, sometimes severe); chronic (lasting a long time); traumatic (a wound caused by trauma); subacute (a wound of moderate duration or severity), dehiscent (burst open or split along suture lines) and diabetic and pressure ulcers

(wounds that appear in pressure areas of skin overlying a body prominence in debilitated patients confined to bed or otherwise immobilized, due to a circulatory defect) help define the origin of the wound and assist the health care professional to prescribe the necessary wound treatment protocol. Clinical studies are provided to support these claims.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 18 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Judith A. Harbour
Regulatory Affairs
Kinetic Concepts, Inc.
P.O. Box 659508
San Antonio, Texas 78265-9508

Re: K992448
Trade Name: V.A.C. Plus
Regulatory Class: II
Product Code: JCX
Dated: September 28, 1999
Received: October 20, 1999

Dear Ms. Harbour:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

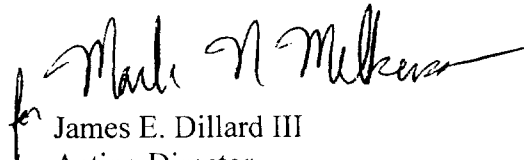
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", with a stylized flourish at the end.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992448Device Name: V.A.C. PLUS

Indications for Use:

The V.A.C. PLUS is a powered suction pump that is intended for use on patients who would benefit from a suction device, particularly as the device may promote wound* healing, including patients who would benefit from vacuum assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or alternating suction pressures.

*The V.A.C. PLUS is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

Caution: Federal law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



for
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(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)